Premarket Notification 510(k) Submission (K112798)	Exhibit #3 510(k) Summary	Project #: 510k-G11Z

Exhibit #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K112798

1. Date of Submission: March 12, 2012.
2. Sponsor

   Shanghai MicroPort Orthopedics Co., Ltd.

   Building 23, No. 588 Tianxiong Rd. Shanghai international medical zone, Pudong new area, Shanghai 201318, P.R. China

   Contact Person: Jason Ma

   Position: Regulatory Affairs Manager

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3. Proposed Device Identification

   Proposed Device Name: Locking compression plate system

   Classification name: Plate, Fixation, Bone

   Classification: II

   Product Code: HRS, HWC

   Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040

   Review Panel: Orthopedic

   Intended Use Statement:

   The Locking Compression Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

4. Predicate Device Identification

   510(k) Number: K101400.

   Product Name: Locking Compression Plate.

   510(k) Number: K100721.

   Product Name: Locking Bone Screw.

5. Device Description

   The applicant device of Locking Compression Plate System consist of plates and screws, made of titanium alloy (Ti6Al4V ELI) which meets the requirements of ASTM F136-08e1, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

   The proposed devices are not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10-6 by the hospital prior to surgery. The validated sterilization method is presented in the user manual.

   The plates vary through lengths and number of plate holes, and the screws vary through diameters and lengths.

Component name	**Specification**
Locking compression plate	Holes number: 2~18, every 1 hole; 20, 24; Length: 44~442mm;
Locking screw	Diameter: 3.5, 5.0mm; Length: 14~120mm.

6. Non-Clinical Test Conclusion

   Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

   - ASTM F543-07 Standard Specification and Test Methods for Metallic Medical Bone Screws
   - ASTM F 382–99 (Reapproved 2008) Standard Specification and Test Method for

Metallic Bone Plates

- ASTM F897–02 (Reapproved 2007) Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and screws

7. Substantially Equivalent Conclusion

Both the proposed and predicate devices have same classification, intended use and materials. The main differences between the proposed and predicate devices are dimension specifications. Mechanical testing were performed on both devices, test results demonstrated that they have similar performances. Therefore the proposed device, Locking Compression Plate System, is determined to be Substantially Equivalent (SE) to the predicate device, Locking Compression Plate as cleared under K101400 and Locking Bone Screw as cleared under K100721, in respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Mr. Jason Ma
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Shanghai, P.R. China, 201318

MAR 2 9 2012

Re: K112798
Trade/Device Name: Locking compression plate system
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 7, 2012
Received: March 22, 2012

Dear Mr. Ma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification 510(k) Submission (K112798)	Exhibit #3 Indications for Use	Project #: 510k-G11Z

Exhibit #3 Indications for Use

510(k) Number: K112798

Device Name: Locking compression plate system

Indications for Use:

The Locking Compression Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112798